

# Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were published in the Federal Register in April 2014.

## Conditional Approvals

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This section displays the original approval. To read the complete approval, please refer to 21CFR Parts 500 and the related Federal Register notices.

Application Number: 141-422

Trade Name: Paccal Vet®-CA1  
Ingredients: Paclitaxel  
Sponsor: Oasmia Pharmaceutical AB  
Approval Date: February 27, 2014  
Status: Rx  
Route: Intravenous injection  
Species: Dog  
Drug Form: Powder for injection  
Concentration: Each milliliter of constituted solution contains 1 mg paclitaxel  
Indications: For the treatment of nonresectable stage III, IV or V mammary carcinoma in dogs that have not received previous chemotherapy or radiotherapy. For the treatment of resectable and nonresectable squamous cell carcinoma in dogs that have not received previous chemotherapy or radiotherapy.  
  
Exclusivity: 7 years  
Patent: Patent Number      Expiration date:  
                 6,642,271              March 15, 2022  
                 7,030,158              November 15, 2022  
                 12/809,259              December 18, 2028

21 CFR 516.1684      79 FR 18156

## Original Approvals

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This section displays the original approval. To read the complete approval, please refer to 21CFR Parts 500 and the related Federal Register notices.

NADA Number: 141-361

Trade Name: Pulmotil® AC  
Ingredients: Tilimicosin phosphate  
Sponsor: Elanco Animal Health a Division of Eli Lilly & Co.  
Approval Date: February 13, 2014  
Status: Rx  
Route: Oral, in drinking water  
Species: Swine  
Drug Form: Aqueous concentrate  
Concentration: 250 mg tilimicosin/mL  
Indications: For the control of swine respiratory disease associated with *Pasteurella multocida* and *Haemophilus parasuis* in groups of swine in buildings where a respiratory disease outbreak is diagnosed.  
  
Exclusivity: 3 years

21 CFR 522.2471      79 FR 18156

NADA Number: 141-420

Trade Name: Tildren®  
Ingredients: Tiludronate disodium  
Sponsor: Ceva Sante Animale  
Approval Date: February 13, 2014  
Status: Rx  
Route: Intravenous infusion  
Species: Horse  
Drug Form: Powder for injection  
Concentration: 500 mg tiludronate disodium  
Indications: For the control of clinical signs associated with navicular syndrome in horses.  
  
Exclusivity: 5 years

21 CFR 516.2473      79 FR 18156

## Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were published in the Federal Register in April 2014.

### NADA Number: 200-468

Trade Name: GentaMed™-P for Poultry Injection  
Pioneer: Garasol® Injection  
Ingredients: Gentamicin Sulfate, USP  
Sponsor: Cross Vetpharm Group Ltd.  
Approval Date: March 14, 2014  
Status: OTC  
Route: Subcutaneously  
Species: Chickens and Turkeys  
Drug Form: Injection  
Concentration: 100 mg/mL  
Indications: Chickens: GentaMed™-P for Poultry Injection is recommended for the prevention of early mortality in day-old chickens associated with *Escherichia coli*, *Salmonella typhimurium*, and *Pseudomonas aeruginosa* susceptible to gentamicin sulfate.  
Turkeys: As an aid in the prevention of early mortality of 1 to 3-day-old turkeys associated with *Arizona paracolon* infections susceptible to gentamicin sulfate.

21 CFR 522.1044 79 FR 21126

### NADA Number: 200-529

Trade Name: XylaMed™  
Pioneer: Rompun® Injectable  
Ingredients: Xylazine  
Sponsor: Cross Vetpharm Group Ltd.  
Approval Date: March 31, 2014  
Status: Rx  
Route: Injection  
Species: Horses and Cervidae (Fallow Deer, Mule Deer, Sika Deer, White-Tailed Deer, and Elk).  
Drug Form: Injectable solution  
Concentration: 100 mg/mL  
Indications: XYLAMED should be used in horses and Cervidae (Fallow Deer, Mule Deer, Sika Deer, White-Tailed Deer, and Elk) when it is desirable to produce a state of sedation accompanied by a shorter period of analgesia.  
Horses: XYLAMED has been used successfully as follows:  

1. Diagnostic procedures-oral and ophthalmic examinations, abdominal palpation, rectal palpation, vaginal examination, catheterization of the bladder and radiographic examinations.
2. Orthopedic procedures, such as application of casting materials and splints.
3. Dental procedures.
4. Minor surgical procedures of short duration such as debridement, removal of cutaneous neoplasms and suturing of lacerations.
5. To calm and facilitate handling of fractious animals.
6. Therapeutic medication for sedation and relief of pain following injury or surgery.
7. Major surgical procedures:
  - a. When used as a preanesthetic to general anesthesia.
  - b. When used in conjunction with local anesthetics.

  
Cervidae: XYLAMED may be used for the following:  

1. To calm and facilitate handling of fractious animals.
2. Diagnostic procedures.
3. Minor surgical procedures.
4. Therapeutic medication for sedation and relief of pain following injury or surgery.
5. As a preanesthetic to local anesthesia.

XYLAMED at the recommended dosages can be used in conjunction with local anesthetics, such as procaine or lidocaine.

21 CFR 522.2662 79 FR 21126

## Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were published in the Federal Register in April 2014.

### Supplemental Approvals

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This section displays the change(s) to the original approval. To read the complete approval, please refer to 21CFR Parts 500 and the related Federal Register notices.

#### NADA Number: 130-185

Trade Name: AMPROL 25% and FLAVOMYCIN  
Ingredients: Amprolium and Bambermycins  
Sponsor: Huvepharma AD  
Approval Date: January 23, 2014

This supplement provides for the use of amprolium at 72.6 to 113.5 g per ton in combination with bambermycins at 1 to 2 g per ton in a Type C feed for prevention of coccidiosis caused by *Eimeria tenella* only, and for increased rate of weight gain and improved feed efficiency in broiler chickens. This supplement also provides for the use of amprolium at 113.5 to 227 g per ton in combination with bambermycins at 1 to 2 g per ton in a Type C feed for prevention of coccidiosis where immunity to coccidiosis is not desired and for increased rate of weight gain and improved feed efficiency in broiler chickens.

21 CFR 558.55 79 FR 18156

#### NADA Number: 141-246

Trade Name: Aquaflor®  
Ingredients: Florfenicol  
Sponsor: Intervet, Inc.  
Approval Date: January 29, 2014

This supplement provides an increase in the maximum daily dose for freshwater-reared finfish other than freshwater-reared warmwater finfish to provide a dosage range of 10-15 mg/kg body weight (BW)/day and to change the conditions of use to permit the use of florfenicol in recirculating aquaculture systems.

21 CFR 558.261 79 FR 18156

### Withdrawal of Approval

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#### NADA Number: 091-582

Sponsor: ADM Alliance Nutrition, Inc.  
Trade Name: Gilt Edge TYLAN Mix  
Ingredients: Tylosin phosphate

This product is withdrawn because the product is no longer manufactured or marketed.

21 CFR 558.625 79 FR 19814

#### NADA Number: 108-484

Sponsor: ADM Alliance Nutrition, Inc.  
Trade Name: HFA Tylosin-10 Plus Sulfa  
Ingredients: Tylosin phosphate and Sulfamethazine

This product is withdrawn because the product is no longer manufactured or marketed.

21 CFR 558.630 79 FR 19814

## Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were published in the Federal Register in April 2014.

### NADA Number: 110-045

Sponsor: ADM Alliance Nutrition, Inc.  
Trade Name: Good Life TYLAN 10 Premix  
Ingredients: Tylosin phosphate

This product is withdrawn because the product is no longer manufactured or marketed.

*21 CFR 558.625 79 FR 19814*

### NADA Number: 110-439

Sponsor: ADM Alliance Nutrition, Inc.  
Trade Name: HFA HYGROMIX 0.48 Medicated Premix  
Ingredients: Hygromycin B

This product is withdrawn because the product is no longer manufactured or marketed.

*21 CFR 558.274 79 FR 19814*

### NADA Number: 128-411

Sponsor: ADM Alliance Nutrition, Inc.  
Trade Name: TYLAN 5 Sulfa Premix  
Ingredients: Tylosin phosphate and Sulfamethazine

This product is withdrawn because the product is no longer manufactured or marketed.

*21 CFR 558.630 79 FR 19814*

### NADA Number: 138-187

Sponsor: Micro Beef Technologies LTD  
Trade Name: TYLAN 40 or 100  
Ingredients: Tylosin phosphate

This product is withdrawn because the product is no longer manufactured or marketed.

*21 CFR 558.625 79 FR 19814*

### NADA Number: 099-468

Sponsor: Ridley USA, Inc. d/b/a Ridley Feed  
Trade Name: Waynextra for Swine  
Ingredients: Tylosin phosphate

This product is withdrawn because the product is no longer manufactured or marketed.

*21 CFR 558.625 79 FR 19814*

### NADA Number: 131-958

Sponsor: Ridley USA, Inc. d/b/a Ridley Feed  
Trade Name: TYLAN Sulfa-G  
Ingredients: Tylosin phosphate and Sulfamethazine

This product is withdrawn because the product is no longer manufactured or marketed.

*21 CFR 558.630 79 FR 19814*

## Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were published in the Federal Register in April 2014.

### NADA Number: 132-136

Sponsor: Ridley USA, Inc. d/b/a Ridley Feed  
Trade Name: Ban-A-Worm II  
Ingredients: Pyrantel Tartrate

This product is withdrawn because the product is no longer manufactured or marketed.

*21 CFR 558.485 79 FR 19814*

### NADA Number: 103-089

Sponsor: Provimi North America, Inc.  
Trade Name: TYLAN 5, 10, 20, or 40  
Ingredients: Tylosin Phosphate

This product is withdrawn because the product is no longer manufactured or marketed.

*21 CFR 558.625 79 FR 19814*

### NADA Number: 118-814

Sponsor: Provimi North America, Inc.  
Trade Name: WORM-BAN 5 or 10  
Ingredients: Pyrantel Tartrate

This product is withdrawn because the product is no longer manufactured or marketed.

*21 CFR 558.485 79 FR 19814*

### NADA Number: 127-508

Sponsor: Provimi North America, Inc.  
Trade Name: HYGROMIX 0.6  
Ingredients: Hygromycin B

This product is withdrawn because the product is no longer manufactured or marketed.

*21 CFR 558.274 79 FR 19814*

### NADA Number: 131-413

Sponsor: Provimi North America, Inc.  
Trade Name: FLAVOMYCIN 0.4 or 2  
Ingredients: Bambermycins

This product is withdrawn because the product is no longer manufactured or marketed.

*21 CFR 558.95 79 FR 19814*

### NADA Number: 133-333

Sponsor: Provimi North America, Inc.  
Trade Name: STAFAC 10  
Ingredients: Virginiamycin

This product is withdrawn because the product is no longer manufactured or marketed.

*21 CFR 558.635 79 FR 19814*

## Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were published in the Federal Register in April 2014.

### NADA Number: 013-214

Sponsor: Virbac AH, Inc.  
Trade Name: PURINA HYGROMIX for Swine  
Ingredients: Hygromycin B

This product is withdrawn because the product is no longer manufactured or marketed.

*21 CFR 558.274 79 FR 19814*

### NADA Number: 042-660

Sponsor: Virbac AH, Inc.  
Trade Name: PURINA Pork-Plus  
Ingredients: Tylosin phosphate and Sulfamethazine

This product is withdrawn because the product is no longer manufactured or marketed.

*21 CFR 558.630 79 FR 19814*

### NADA Number: 043-387

Sponsor: Virbac AH, Inc.  
Trade Name: PURINA Hog Plus II  
Ingredients: Tylosin phosphate

This product is withdrawn because the product is no longer manufactured or marketed.

*21 CFR 558.625 79 FR 19814*

### NADA Number: 099-767

Sponsor: Virbac AH, Inc.  
Trade Name: PURINA TYLAN 40 Plus Sulfamethazine  
Ingredients: Tylosin phosphate and Sulfamethazine

This product is withdrawn because the product is no longer manufactured or marketed.

*21 CFR 558.630 79 FR 19814*

### NADA Number: 132-574

Sponsor: Virbac AH, Inc.  
Trade Name: PURINA Check-R-Ton LI  
Ingredients: Lincomycin hydrochloride

This product is withdrawn because the product is no longer manufactured or marketed.

*21 CFR 558.325 79 FR 19814*